

Applicants: Lionel Vedrine  
Serial No.: 10/520,981  
Filing Date: August 29, 2005  
Docket No.: P-5753 (102-627 PCT/US RCE II)  
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**REMARKS**

Reconsideration of the application is respectfully requested.

Claims 1 and 5-7 are in the application. Through this Amendment, claims 1, 5 and 7 have been amended.

In the Official Action, the Examiner objected to the drawings of the application for allegedly failing to show "at least one secondary flange and the at least one secondary tab". In response, it is noted that in the Specification, two sets of tabs are discussed, namely tabs 29 and tabs 39. In addition, two different flanges are discussed, namely flange 27 and flange 45. These elements are discussed for example at p. 5, ll. 15-17 and p. 5, ll. 34-36 of the application as filed. As is common practice when two sets of the same elements are discussed in claims, reference is made to distinguish one set of elements from the other. With respect to the claims of the subject application, the term "secondary" was used in claim 7 to distinguish one set of tabs and flange from those set forth in claim 1. In particular, the at least one tab in claim 1 corresponds to tabs 39 in the Specification and the flange in claim 1 corresponds to flange 45 in the Specification. With respect to the at least one secondary flange, this corresponds to flange 27 and the at least one secondary tab corresponds to tabs 29. All of these features are shown in at least in Fig. 6 of the subject application. It is respectfully submitted that all claimed features are shown in the figures of the application.

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The Examiner objected to the Specification with respect to the claimed term "spring means" found in claim 5. Claim 5 has been amended to recite a "spring". The Examiner also asserted that proper antecedent basis for the claimed subject matter is not found in the Specification. Specifically, the Examiner asserted that the Specification "fails to disclose a device as having a needle-supporting part comprising at least one secondary flange and as having at least one secondary tab able to engage with the secondary flange of the needle-supporting part". As indicated above, the secondary flange and secondary at least one tab are clearly disclosed. The needle-supporting part is part 6 of the Specification. It is further stated that only the secondary flange is set forth in claim 7 as being on the needle-supporting part. The secondary at least one tab is part of the device. It is respectfully submitted that the Specification is in accord with standard U.S. practice.

The Examiner objected to claims 5 and 7. In particular, the Examiner raised an objection to the term "spring means". As indicated above, the term "spring means" has been replaced with the term --spring--. Further, the Examiner noted that the number "6" was inadvertently not deleted in claim 7. In response, the number "6" has been deleted. It is respectfully submitted that claims 5 and 7 are in accord with standard U.S. practice.

The Examiner rejected claims 1 and 5-7 under 35 U.S.C. §112, second paragraph, as being allegedly indefinite for failing to particularly point out and distinctly claim the subject

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matter which Applicant regards as the invention. In particular, with respect to claim 1, the Examiner indicated that the phrase "releasing it" in the last line of claim 1 is unclear. In response, claim 1 has been amended to replace the term "it" with the term --the flange--. Also, the Examiner objected to the phrase "unlock it" in line 10 of claim 7. This phrase has been replaced with the term --unlock the secondary flange--.

The Examiner also objected to the use of "said tab" in claim 1 and "said secondary flange" and "said secondary tab" in claim 7. In response, claims 1 and 7 have been amended. It is respectfully submitted that the claims, as amended, are in accord with 35 U.S.C. 112.

The Examiner rejected claims 1, 5 and 6 under 35 U.S.C. §103(a) as being allegedly unpatentable over Barker et al. (U.S. Patent No. 6,981,963) in view of Pfleger (U.S. Patent No. 4,929,230). The Examiner admitted that "Barker et al. are silent on the specifics of the piston being so shaped to have a blind hole located adjacent a peripheral portion where the peripheral portion of the piston is deflected into the blind hole to allow the product to pass between the piston and the container." The Examiner relied on Pfleger for allegedly overcoming this deficiency. The Examiner stated in formulating the rejection:

Since the use of the piston of Pfleger does not require and *would not work with the fluid passage (160) of Barker et al.*, it would be obvious to one having ordinary skill at the time the invention was made that the substitution of the piston of Barker et al. with the piston of Pfleger would not require and would not work

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with a fluid passage, and thus the device of Barker et al. would be modified to not include this fluid passage.

(Emphasis added).

The Examiner's assertions are respectfully traversed.

As noted and admitted by the Examiner, the Pfleger piston "would not work with the fluid passage (160) of Barker et al". It is clear that Barker et al. must be altered to work with the Pfleger piston, as admitted by the Examiner. Under *KSR*, if a proposed modification or combination of the prior art would change the principle of operation of the prior invention being modified, than the teachings and the references are not sufficient to render the claims *prima facie* obvious. See, MPEP 2143.01(VI). Thus, under *KSR* the manner in which a reference is operated can not be modified. Under *KSR* it is also stated, "[t]he mere fact that references can be combined or modified does not render the resultant combination obvious unless the results would have been predictable to one of ordinary skill in the art." See, MPEP 2143.01(III). The Examiner is suggesting a complete re-design of Barker et al. to allow for the operation of Pfleger. Barker et al. and Pfleger are completely different designs, as admitted by the Examiner. The references can not be modified as suggested by the Examiner under *KSR*.

It is also noted that Barker et al. is directed to a pre-filled safety injector which includes a two-chamber cartridge for mixing dry and wet components. The Barker et al. injector includes a

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mid seal 170 which coacts with fluids passage 160 to allow the liquid component 154 to bypass the mid seal 170 through the fluid passage 160 and mix with the dry component 158. As shown in Fig. 14, the mixing occurs with the mid seal 170 located spaced from the front seal 180 (see Fig. 12).

Pfleger discloses a piston 33 which includes a hollow shape 48 that is inwardly deflectable. With Pfleger, sufficient pressure must be built up to allow the wall 35 of the piston 33 to collapse to permit bypass flow. (Col. 5, ll. 20-24). As shown in Figs. 1 and 3, the piston 33 is at the base of the syringe barrel. The base of the syringe holds the piston 33 to permit the proper pressure build up. (Col. 5, ll. 25-34). Where two of the pistons 33, 33a are used, pressure is still built up at the base of the syringe barrel to obtain fluid delivery. (Col. 6, ll. 11-24).

It is evident that with the design of Pfleger, sufficient pressure must be provided to enable bypass of fluid about the piston 33. With using the Pfleger piston in a liquid/dry dual chamber combination, such as that shown in Barker et al., it is unclear how the Pfleger piston would operate. Particularly, the Pfleger piston would have to bottom out against the dry component before liquid may be introduced into the dry chamber. With the Pfleger piston bottomed out, it is unclear if sufficient volume would exist in the dry chamber to house a liquid mixture of the two components. The Pfleger piston operates completely differently from the mid seal 170 of Barker et al. Because of the necessary pressure to deflect the Pfleger piston, it is respectfully submitted

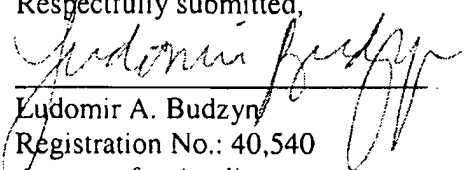
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that the Pflieger piston would not work in a liquid/dry injector, such as Barker et al., regardless of the barrel configuration. It is respectfully submitted that claim 1, along with dependent claims 5-7, are patentable over Barker et al. and Pflieger, each taken alone or in combination.

Applicant notes the indication of allowability of claim 7.

Favorable action is earnestly solicited. If there are any questions or if additional information is required, the Examiner is respectfully requested to contact Applicant's attorney at the number listed below.

Respectfully submitted,

  
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